REMARKS

I. Claim Amendments

Upon entry of this amendment, claims 45-64 will be pending in the instant application. Claims 1-44 were previously canceled. Claims 45, 48, 51-56, 58, and 60-63 are currently amended. Claim 45 has been amended to remove "for treating a pelvic inflammatory condition" and "a polyunsaturated fatty acid." Claim 64 has been added to depend from claim 45 and further comprise "a polyunsaturated fatty acid." Claims 48, 51-56, and 58 have been amended to clarify the relationship between the added elements and their antecedent bases. Claims 60-63 have been amended and are now directed to methods of treating endometriosis. No new matter has been added by these amendments.

II. Priority

Applicant thanks the Examiner for acknowledging Applicant's amended priority claim.

The Examiner has alleged that PCT '476 fails to provide adequate support or enablement as required by 35 U.S.C. § 112, first paragraph, for claim 45. (*See* Office Action, p. 2.) Thus, the Examiner has not afforded the instant application an earlier filing date. Applicant respectfully disagrees with this assessment.

The Examiner stated that PCT '476 does not have support for the limitations "pelvic inflammatory condition," "folic acid," or "a polyunsaturated fatty acid." (*Id.*) However, PCT '476 states, "Folic acid may be added to certain of the present formulations…" (p. 6, lines 31-32.) Additionally, Example 1 in PCT '476 includes folic acid as an ingredient in a composition of the invention. Finally, claims 29 and 33 are directed to compositions comprising folic acid. Therefore, PCT '476 does contain support for folic acid.

Claim 45 has been amended to remove the reference to a pelvic inflammatory condition. Claim 45 has also been amended to remove "a polyunsaturated fatty acid" from the Markush group. New claim 64 has been added to depend from claim 45 and further comprise "a polyunsaturated fatty acid."

Applicant respectfully submits that PCT '476 provides support and enablement of at least claim 45. As acknowledged by the Examiner, PCT '476:

> "teaches proteoglycan compositions for treatments of inflammatory conditions comprising a sulfated proteoglycan such as chondroitin sulfate and one or more of a hexosamine sulfate such as D-glucosamine sulfate, a flavone such as quercetin, an refined kernel olive oil that increases absorption, S-adenosylmethionine (SAM), a histamine-1 receptor antagonist, a histamein-3 receptor agonist, a CRH antagonist, caffeine and a polyamine (abstract). Theoharides teaches other suitable proteoglycans including keratin sulfate, dermatan sulfate and sodium hyaluronate (page 6, lines 1-2), other suitable flavones including myricetin, genistein and kaempferol (page 6, lines 10-11), suitable histamine-1 receptor antagonists including hydroxyzine, azelastine, azatadine and cyproheptadine (page 7, lines 1-3). Theoharides further teaches preferred concentrations of the proteoglycan, hexosamine sulfate and flavones to be 10-3000 mg, SAM to be 3-1000 mg and unrefined kernel olive oil to be 900-1200 mg (page 7, lines 21-28). Example 10 exemplifies the particular combination of chondroitin sulfate, quercetin and hydroxyzine and Example 14 exemplifies the particular combination of chondroitin sulfate, myricetin and hydroxyzine."
>
> (Office Action, p. 10.)

Therefore, PCT '476 provides support for each element of claim 45. As a result, Applicant respectfully requests that priority be afforded to the instant application at least to January 3, 2002.

III. **Claim Rejections**

A. Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

Claims 60-63 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. (Office Action, p. 7.) Specifically, the Examiner stated that the specification "does not describe a sufficient number of species as to convey possession of the entire genus encompassed by pelvic inflammatory conditions." (*Id.*)

Claims 60-63 have been amended and are now directed to methods of treating endometriosis. As noted by the Examiner, support for endometriosis is found in ¶ [0034]. (*See* Office Action, 7.)

Applicant believes the amended claims comply with 35 U.S.C. § 112, first paragraph. Therefore, Applicant respectfully requests that the rejection be withdrawn.

B. Claim Rejections – 35 U.S.C. § 112, 2nd Paragraph

Claims 48 and 51-59 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. (Office Action, pp. 7-8) Specifically, the Examiner stated that claims 48 and 51-59 lack clarity. (*See id.*) Claims 48 and 51-59 have been amended to clarify the relationship between the added elements and their antecedent bases.

Applicant believes the amended claims comply with 35 U.S.C. § 112, second paragraph. Therefore, Applicant respectfully requests that the rejection be withdrawn.

C. Claim Rejections – 35 U.S.C. § 102 in view of Florio

The Examiner rejected claims 45-48 and 51-59 under 35 U.S.C. § 102(b) as allegedly being anticipated by Florio (WO 97/21434). Applicant respectfully traverses this rejection.

The Examiner has stated that Florio "teaches nutritional supplements for treating arthritis comprising gamma linolenic acid, the polyunsaturated fatty acids eicosapantaenoic acid (EPA) and docosahexaneoic acid (DHA), the sulfated proteoglycans chondroitin sulfate, N-acetyl glucosamine sulfate and glucosamine sulfate, and manganese aspartate (abstract)." (Office Action, p. 9.) Gamma linolenic acid, EPA, and DHA are polyunsaturated fatty acids. Florio teaches that these polyunsaturated fatty acids are part of the "essential nutritional supplements of the dietary regimen of the invention." Thus, these polyunsaturated fatty acids are required by Florio.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As noted

above, claim 45 has been amended to remove the polyunsaturated fatty acid from the Markush group. Thus, a polyunsaturated fatty acid is not required by claim 45. Therefore, because the polyunsaturated fatty acids are required by Florio, Florio does not disclose each and every element of claim 45 and cannot anticipate claim 45.

Claims 46-48 and 51-59 are dependent claims that also do not require a polyunsaturated fatty acid. Therefore, Florio also does not anticipate claims 46-48 and 51-59.

Applicant respectfully submits that the rejection of claims 45-48 and 51-59 has been overcome. Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) in view of Florio be withdrawn.

D. Claim Rejections – 35 U.S.C. § 102 in view of Theoharides

The Examiner rejected claims 45-56 and 58 under 35 U.S.C. § 102(b) as being anticipated by Theoharides (WO 02/060393). Applicant respectfully traverses this rejection.

WO 02/060393 is the publication of PCT '476, the application to which the instant application claims priority. As discussed above, claim 45 has been amended to remove "a polyunsaturated fatty acid" from the Markush group and to remove the reference to a pelvic inflammatory condition. As also discussed above, PCT '476 contains support for each and every element of claim 45. PCT '476 also provides support and enablement of claims 46-56 and 58. As acknowledged by the Examiner, PCT '476:

> "teaches proteoglycan compositions for treatments of inflammatory conditions comprising a sulfated proteoglycan such as chondroitin sulfate and one or more of a hexosamine sulfate such as D-glucosamine sulfate, a flavone such as quercetin, an refined kernel olive oil that increases absorption, S-adenosylmethionine (SAM), a histamine-1 receptor antagonist, a histamein-3 receptor agonist, a CRH antagonist, caffeine and a polyamine (abstract). Theoharides teaches other suitable proteoglycans including keratin sulfate, dermatan sulfate and sodium hyaluronate (page 6, lines 1-2), other suitable flavones including myricetin, genistein and kaempferol (page 6, lines 10-11), suitable histamine-1 receptor antagonists including

> hydroxyzine, azelastine, azatadine and cyproheptadine (page 7, lines 1-3). Theoharides further teaches preferred concentrations of the proteoglycan, hexosamine sulfate and flavones to be 10-3000 mg, SAM to be 3-1000 mg and unrefined kernel olive oil to be 900-1200 mg (page 7, lines 21-28). Example 10 exemplifies the particular combination of chondroitin sulfate, quercetin and hydroxyzine and Example 14 exemplifies the particular combination of chondroitin sulfate, myricetin and hydroxyzine."
>
> (Office Action, p. 10.)

Thus, PCT '476 teaches each and every element of claims 45-56 and 58 and priority is properly claimed in the instant application to PCT '476. Therefore, WO 02/060393 does not anticipate claim 45.

Applicant respectfully submits that the rejection has been overcome in view of the foregoing amendments and arguments. Applicant respectfully requests that the rejection of claims 45-56 and 58 under 35 U.S.C. § 102(b) be withdrawn.

E. Claim Rejections – 35 U.S.C. § 102 in view of Crea

The Examiner rejected claims 60-63 under 35 U.S.C. § 102(a/e) as allegedly being anticipated by Crea (US 2004/0039066). (Office Action, p. 11.) Applicant respectfully traverses this rejection.

Claims 60-63 have been amended and are now directed to methods of treating endometriosis. As noted by the Examiner, support for endometriosis is found in ¶ [0034]. (*See* Office Action, 7.) Although the specification of the instant application states "[p]elvic inflammatory conditions, such as presents in endometriosis, can also be treated with the inventive compositions," the Examiner stated that the specification of the instant application "does not describe a sufficient number of species as to convey possession of the entire genus encompassed by pelvic inflammatory conditions." (*Id.*)

Crea states that it provides a method of treating an inflammatory condition that

> "results from a condition selected from the group consisting of asthma, psoriasis, skin sunburn, inflammatory pelvic disease, inflammatory bowel disease, urethritis, uvitis, senusitis, pneumonitis, encephalitis, meningitis, myocarditis, nephritis, osteomyelitis, myositis, hepatitis, gastritis, enteritis, dermatitis, gingivitis, appendicitis, pancreatitis, cholocystitis and cholangititis."
>
> (*See* Crea, ¶¶ [0058] and [0060].)

Crea does not describe a single species that would convey possession of the entire genus encompassed by inflammatory pelvic disesase. Furthermore, Crea neither mentions nor enables treatment of endometriosis. Thus, Crea does not teach a method of treating inflammatory pelvic disease or endometriosis. Because Crea does not teach each and every element of any of claims 60-63, it does not anticipate claims 60-63.

Applicant respectfully submits that the rejection has been overcome in view of the foregoing amendments and arguments. Applicant respectfully requests that the rejection of claims 60-63 under 35 U.S.C. § 102(b) be withdrawn.

F. Claim Rejections – 35 U.S.C. § 103(a) in view of Lindsberg

The Examiner rejected claims 45-48 and 51-57 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lindsberg (U.S. 2006/0210551). Applicant respectfully traverses this rejection.

As discussed above, PCT '476 contains support for claim 45. Claim 45 has been amended to remove a polyunsaturated fatty acid from the Markush group and to remove the reference to a pelvic inflammatory condition. As also discussed above and as acknowledged by the Examiner, PCT '476:

> "teaches proteoglycan compositions for treatments of inflammatory conditions comprising a sulfated proteoglycan such as chondroitin sulfate and one or more of a hexosamine sulfate such as D-glucosamine sulfate, a flavone such as quercetin, an refined kernel olive oil that increases absorption, S-

> adenosylmethionine (SAM), a histamine-1 receptor antagonist, a histamein-3 receptor agonist, a CRH antagonist, caffeine and a polyamine (abstract). Theoharides teaches other suitable proteoglycans including keratin sulfate, dermatan sulfate and sodium hyaluronate (page 6, lines 1-2), other suitable flavones including myricetin, genistein and kaempferol (page 6, lines 10-11), suitable histamine-1 receptor antagonists including hydroxyzine, azelastine, azatadine and cyproheptadine (page 7, lines 1-3). Theoharides further teaches preferred concentrations of the proteoglycan, hexosamine sulfate and flavones to be 10-3000 mg, SAM to be 3-1000 mg and unrefined kernel olive oil to be 900-1200 mg (page 7, lines 21-28). Example 10 exemplifies the particular combination of chondroitin sulfate, quercetin and hydroxyzine and Example 14 exemplifies the particular combination of chondroitin sulfate, myricetin and hydroxyzine."
>
> (Office Action, p. 10.)

Thus, PCT '476 teaches each and every element of claim 45 and priority is properly claimed in the instant application to PCT '476. PCT '476 also contains support for dependent claims 46-48 and 51-57. Therefore, the priority date of the instant application is at least as early as January 2, 2002, the international filing date of PCT '476. This is well before the publication date of September 21, 2006 for Lindsberg. Thus, Lindsberg cannot be prior art under 35 U.S.C. § 102(a)/(b).

Lindsberg was filed February 13, 2004 as the national stage application of PCT/FI04/00072, which claims priority to U.S. Provisional Application No. 60/446,990, which was filed February 13, 2003. Even if the earliest priority date of Lindsberg under 35 U.S.C. § 102(e) is February 13, 2003, Lindsberg was filed well over a year after the January 2, 2002 filing date of PCT '476. As such, Lindsberg cannot render the claims of the instant application obvious.

Applicant respectfully submits that the rejection has been overcome in view of the foregoing amendments and arguments. Applicant respectfully requests that the rejection of claims 45-48 and 51-57 under 35 U.S.C. § 103(a) be withdrawn.

G. Claim Rejections – 35 U.S.C. § 103(a) in view of Theoharides

The Examiner has rejected claims 57 and 59 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Theoharides (WO 02/060393). Applicant respectfully traverses this rejection.

As discussed above, WO 02/060393 is the publication of PCT '476, the application to which the instant application claims priority. As also discussed above, PCT '476 provides support for independent claim 45. Claims 57 and 59 are dependent claims. As acknowledged by the Examiner, WO 02/060393 – *i.e.*, PCT '476 – teaches the elements of claims 57 and 59. (Office Action, p. 12.) Therefore, because priority is properly claimed in the instant application to PCT '476, and support for claims 57 and 59 is found in PCT '476, WO 02/060393 does not render claims 57 and 59 obvious.

Applicant respectfully submits that the rejection has been overcome in view of the foregoing amendments and arguments. Applicant respectfully requests that the rejection of claims 57 and 59 under 35 U.S.C. § 103(a) be withdrawn.

IV. **Double Patenting**

The Examiner rejected claims 45-59 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-13 and 15-27 of U.S. Patent No. 6,984,667.

The Examiner also rejected claims 45-50, 53, and 55 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-2 of U.S. Patent No. 7,115,278.

Applicant is filing a terminal disclaimer for U.S. Patent Nos. 6,984,667 and 7,115,278 with this Response.

CONCLUSION

Applicant believes the rejections set forth in the Office Action have been overcome and that the application is in condition for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued.

Applicant believes no fees are due with this Amendment and Response. However, if such a fee is due, or a credit is owed, the Director is hereby authorized to make them to our Deposit Account No. 08-0219, under Order No. 2003133.00125US11.

The Examiner is encouraged to call the undersigned at the telephone number given below to move this application towards allowance.

Respectfully submitted,

Dated: July 17, 2009

/David A. Giordano/
David A. Giordano
Registration No.: 64,480
Attorney for Applicant

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000 (telephone)
(617) 526-5000 (facsimile)